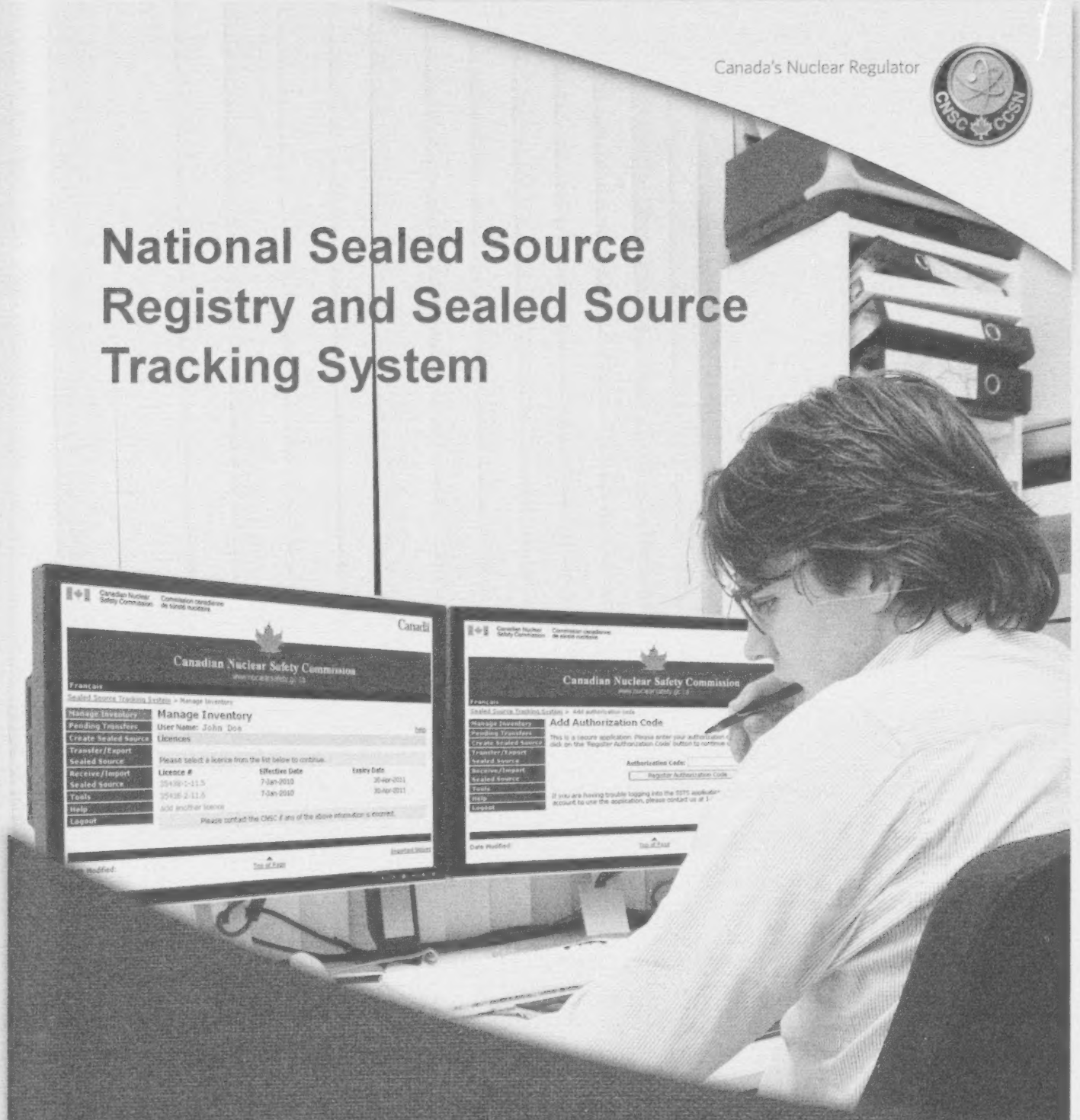
Canada's Nuclear Regulator

National Sealed Source Registry and Sealed Source Tracking System



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Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire

Canada

National Sealed Source Registry and Sealed Source Tracking System - 2008 Annual Report

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Canadian Nuclear Safety Commission
280 Slater Street
P.O. Box 1046, Station B
Ottawa, Ontario K1P 5S9
CANADA

Tel.: 613-995-5894 or 1-800-668-5284 (in Canada only)
Facsimile: 613-995-5086
Email: info@cnsc-ccsn.gc.ca
Web site: nuclearsafety.gc.ca

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Executive Summary

This report describes developments in the Canadian Nuclear Safety Commission's (CNSC) National Sealed Source Registry and Sealed Source Tracking System for the period of January 1, 2008, to December 31, 2008. The CNSC was the first nuclear regulator among G8 countries to develop a national registry and to implement a Web-based tracking system, along with enhanced export and import controls for high-risk sealed sources. Previous annual reports were issued in 2006 and 2007.

The CNSC manages the national database inventory of high-risk radioactive sealed sources. The National Sealed Source Registry (NSSR) helps the CNSC maintain detailed information and track the locations of all high-risk radioactive sealed sources in Canada. This system, in conjunction with regulatory compliance operations, increases the security and safety of those sources.

The NSSR's high-risk source tracking component is called the Sealed Source Tracking System (SSTS), and is an electronic add-on that provides licensees and CNSC staff members with a more convenient and efficient way to report any movement of sealed sources.

The CNSC has established and implemented effective and efficient regulatory systems, to ensure the safety and security of high-risk radioactive sources and devices in Canada. The NSSR and SSTS strengthen the CNSC's and Canada's controls on high-risk radioactive sources. These systems contain information on the movement and location within the country of high-risk sources, from their manufacture to their final disposition (cradle-to-grave approach). All high-risk radioactive sources are closely tracked, except those under the control of the Department of National Defence, which is exempted from CNSC regulation. The CNSC designed and implemented the NSSR and the SSTS in a manner consistent with the provisions of the International Atomic Energy Agency's (IAEA) *Code of Conduct on the Safety and Security of Radioactive Sources* (the Code).

The CNSC began to develop the NSSR and SSTS in 2004 and 2005. The project team designed the system, developed software requirements, and accumulated initial data about radioactive sealed sources in Canada. Also, in order to implement the SSTS, the CNSC had to amend its licences, to make it mandatory for licensees to report radioactive source transactions. Accordingly, in mid-2005, CNSC staff asked the Commission to amend 278 licences that listed high-risk radioactive sealed sources. Licensees were notified and consulted, and the Commission agreed to amend these licences; the source tracking of high-risk sealed sources became a legal requirement on January 1, 2006.

The NSSR and the SSTS evolved in 2006, with the addition of a Web-based system for source tracking, allowing for a simplified method of secure, online reporting. Ongoing communication and consultation with licensees, as well as the establishment of a system of performance measures, has helped guide CNSC staff in ensuring that operations are conducted in an efficient and secure manner.

Throughout 2008, the NSSR continued to be populated with high-risk (categories 1 and 2) source information, as licensees reported their transactions. In late 2007, the CNSC started compiling data on sealed sources belonging to categories 3, 4 and 5. This process continued in 2008, as licensees gradually provided inventory information on category 3, 4 and 5 sources. These will be added to the NSSR, following a review and verification of the current source inventory details, as submitted by

licensees on an annual basis. The CNSC is designing a Web-based module, whereby licensees will be able to submit and update their yearly source inventories using a secure online reporting system. The CNSC will be able to maintain data on all sealed sources used, stored or transported in Canada. An online reporting system for categories 3, 4 and 5 is planned for 2009.

By the end of December 2008, the NSSR had information on 19,847 radioactive sealed sources of all categories in Canada. This represented an increase of 28% over 2007. For 2008, the SSTS was tracking 2,410 sources of category 1, and 12,881 sources of category 2. The other 4,556 sources in the NSSR belonged to categories 3, 4 and 5, which are not subject to mandatory tracking. The SSTS registered more than 40,000 transactions of all types throughout the year, which represents a 3% increase over 2007.

Introduction:

What is a sealed source?

A radioactive sealed source is defined in CNSC Nuclear Substances and Radiation Devices Regulations as:

"A radioactive nuclear substance in a sealed capsule or in a cover to which the substance is bonded, where the capsule or cover is strong enough to prevent contact with or the dispersion of the substance under the conditions for which the capsule or cover is designed."

Why is it important to track sealed sources?

High-risk sealed sources contain potentially dangerous radioactive material. If these sealed sources are misused, misplaced, stolen or carelessly abandoned, injuries and fatalities can occur.

Closely monitoring the movement of sealed sources through a national registry complies with the IAEA's Code of Conduct on the Safety and Security of Radioactive Sources. This Code aims to enhance the safety and security of radioactive sources throughout the world.

The CNSC's online Sealed Source Tracking System (SSTS) is the first of its kind, proving once again that Canada is a world leader in nuclear safety.

What does the Sealed Source Tracking System do?

The SSTS keeps track of movements of high-risk radioactive sealed sources from one location to another, and can be accessed via the internet. This is done throughout the life cycle of the source.

Licensees can now report the following activities online:

- Receipt;
- Transfer;
- Import; and
- Export.

What is needed to use the Sealed Source Tracking System?

Only those CNSC licensees authorized to possess high-risk sealed sources can use this system. These licensees must obtain an authorization code from their CNSC licensing officer.

Licensees using the system are required to provide:

- The date of transaction;
- Serial number of source;
- Where the source is coming from - CNSC licence number (if applicable) and address;

- Where the source is going - CNSC licence number (if applicable) and address;
- Model name and serial number of the prescribed equipment containing the source (such as radiography camera, irradiator, teletherapy machine); and
- Model and name of the source assembly (in the case of radiography camera).

Transfers and exports must be reported at least 7 days before the actual shipment takes place.

Receipts and imports must be reported within 48 hours of reception.

What are the benefits of the Sealed Source Tracking System?

- Alerts the shipper if the recipient is not licensed by the CNSC;
- Alerts the shipper if the receiving location is not authorized;
- Alerts the CNSC if the source has not been received at its destination;
- Helps the CNSC to monitor the possession and movement of sealed sources, and prevent any unauthorized possession of sources which could harm Canadians;
- It's quick, easy and convenient.

More information on: Sealed Source Tracking System

1. Past to present

In 2004, the International Atomic Energy Agency (IAEA) published the *Code of Conduct on the Safety and Security of Radioactive Sources*. The CNSC participated in meetings to draft the Code, and determined that **source tracking**, a **national source registry**, and **source export licensing** at the CNSC needed to be bridged, in order to make Canadian practice conform to the provisions of the Code. Accordingly, the CNSC began to address these gaps, commencing with the development of the NSSR and SSTS. The NSSR and SSTS were implemented in January 2006, while the export licensing provisions conforming to the Code were implemented in April 2007.

The CNSC maintains a specific regulatory framework for the licensing of all sealed sources and radiation devices. The CNSC's Nuclear Substances and Radiation Devices licences and the Class II Nuclear Facilities and Prescribed Equipment licences state the specific radioactive nuclear substance and the maximum quantity of that nuclear substance allowable for each type of radiation device. The NSSR contains the serial numbers of each high-risk radioactive sealed source, as well as specific information on the radiation device (or other type of prescribed equipment) containing the sealed source, and the location and number of devices (or equipment) of each type held by a licensee.

2. Description of the NSSR and SSTS

The SSTS is a secure information management program used to populate the NSSR, and allows licensees to report their source transactions online. The NSSR enables the CNSC to build an accurate and secure inventory of sealed sources in Canada, starting with those that are classified as

high-risk. The information is as current as the reporting timeframes required by the licence (e.g. reporting within two days of receipt, and seven days in advance of any transfer).

The NSSR contains information about the numbers and types of high-risk radioactive sealed sources, radiation devices and other prescribed equipment in Canada. More complete information concerning moderate and low-risk sources is planned to be included in the NSSR by the end of 2009.

Sealed sources are categorized by the IAEA[1] into one of five categories (see Appendix 1), with categories 1 and 2 being designated as high-risk. Currently, the NSSR contains data about all category 1 and 2 sources in Canada, along with data on a limited number of sources belonging to categories 3, 4 and 5. Category 3 sources are moderate-risk, and categories 4 and 5 sources are low-risk. As first priority, the CNSC has focused its efforts to accurately capture the data about high-risk (or risk-significant) sources.

3. Major developments in 2008

3.1 System design enhancements

Based on the comments and suggestions received from system users, the CNSC designed and tested modifications to the secure, Web-based SSTS system in 2007. The modifications include a more user friendly interface — through the availability of drop-down listings of information — , improved reference tools, and the incorporation of CNSC's new Web page design. Version 2 of the SSTS was introduced in June 2008. In that same year (2008), the SSTS recorded 3,187 online source transfers, compared to only 873 recorded for 2007.

3.2 Outreach program

In April 2008, the CNSC held meetings with a representative from the Australian Radiation Protection and Nuclear Safety Agency, to discuss the risk-informed regulation of sealed sources. The main objectives of the meetings were to exchange information and experience regarding the regulation of high-risk sources, and to describe the CNSC's development of the NSSR and SSTS system.

Individual meetings were also held with major distributors of sealed sources, to discuss issues pertaining to the use of the system and population of the NSSR.

3.3 International presentations

In June 2008, the CNSC participated in the Global Initiative to Combat Nuclear Terrorism Conference on Security of Radioactive Sources. Presentations were made on the implementation of the Code of Conduct on the Safety and Security of Radioactive Sources, and its supplementary Guidance on the Import and Export of Radioactive Sources. During this meeting, CNSC staff gave a presentation on the use in Canada of the National Sealed Source Registry and the Sealed Source Tracking System.

4. Performance management

4.1 Establishing performance measures

In 2007, in order to gauge the effectiveness of the SSTS program and the accuracy of the data in the system, the CNSC designed and implemented a project to establish performance measures. This involved conducting inspections to physically verify licensee inventories of category 1 and 2 sources, source movement and locations, against licensee-entered information in the NSSR and SSTS. This project became part of routine compliance inspection activities in 2008. The results demonstrated that all sources in licensees' inventories were accounted for in the system.

4.2 Data standardization issues

Some issues identified in 2007, regarding data inconsistencies resulting from a non-standard nomenclature in identifying radiography sealed source assemblies, were examined during performance evaluations and inspections in 2007 and 2008. The frequency of these inconsistencies was significantly reduced by the implementation of system enhancements, in June 2008.

4.3 Compliance verification

The inspection datasheets used by CNSC inspectors were amended to include the SSTS tracking requirement. CNSC inspectors began to use SSTS data in their inspection visits in 2008. This procedure provides ongoing compliance and performance data evaluation.

5. Forthcoming improvements and objectives

5.1 Updates and improvements to NSSR and Web SSTS

The licensees had previously indicated that too much information has to be keyed into the SSTS Web pages, which increased the chances of data entry errors in the system. These usually represented inconsistencies in data format. Although the SSTS Web interface was purposely designed to require source data to be keyed in (as a measure to ensure consistency in properly identifying the sources), the problem was corrected by creating more user-friendly drop-down menus and pick lists. This was enabled at the same time with the implementation of Government of Canada's e-Pass secure log-in technology to access the SSTS, which provides high level system security.

This improvement to the user interface — along with others, such as e-mail notification, a licence lookup tool, unit converters (between SI units and non-SI units), and a decay activity calculator — were thoroughly evaluated and integrated into the version 2 of the SSTS, which was released in June 2008.

5.2 Ongoing documentation

As enabling tools are created and modified, procedures will be written, revised and added as part of the NSSR/SSTS Manual.

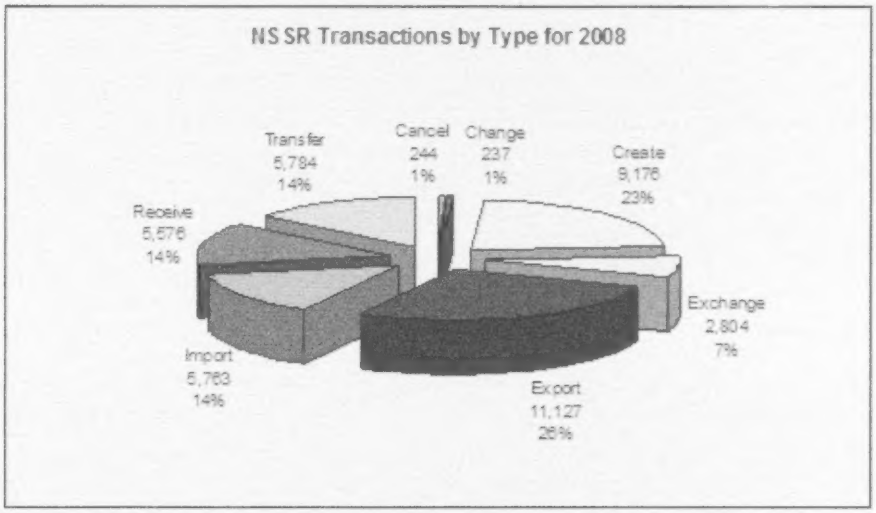
5.3 Population of the NSSR with Category 3, 4 and 5 sources

In late 2007, the CNSC started compiling data on sealed sources of categories 3, 4 and 5. Licensees are gradually providing inventory information on sources belonging to category 3, 4 and 5, which will be added to the NSSR following a review and verification of the current source inventory details (submitted by licensees on an annual basis). The CNSC is designing a Web-based module, whereby licensees will be able to submit and update their yearly source inventories using a secure online reporting system. The CNSC will be able to maintain data on all sealed sources used, stored or transported in Canada. An online reporting system for categories 3, 4 and 5 is planned for 2009. This project continued through 2008; once completed in 2009, it will populate the NSSR with data on every category of sealed sources in Canada.

6. Operational data

Throughout 2008, the NSSR continued to be populated with high-risk source information, as licensees reported their transactions. The following operational data sets encompass the entire National Sealed Source Registry and Sealed Source Tracking System. The data includes all sources reported by mail, fax and e-mail, as well as Web transactions (transfers, receipts, imports, exports, cancellations, changes and creations).

Chart #1: Chart of transactions, by type:



Create: Creation of a new source manufactured in Canada
Change: Data change (e.g. to reference date or source identity)
Cancel: Data change due to unforeseen circumstances (export and shipment cancellations and delayed transfers)
Exchange: The replacement of one source for another in a device or prescribed equipment, at a licensed location
Export: Represents sources shipped out of Canada
Import: Represents sources shipped into Canada
Receive: Represents sources received by licensees at licensed locations
Transfer: Represents the number of sources transferred within Canada, between licensees and licensed locations

All category 1 and 2 sources are subject to mandatory source tracking. Some category 3, 4 and 5 sources have been reported by licensees as an integral part of their overall inventory. This number increased in 2008, as some sources naturally decayed from higher categories and more licensees' inventories were added to the system.

Table 1: National Sealed Source Registry Statistics

	NSSR Statistics	As of Dec 31, 2006	As of Dec 31, 2007	As of Dec 31, 2008
1	Number of NSSR transactions	**30,167**	**39,645**	**40,711**
2	Number of sources in NSSR (all categories) in Canada	**7,150**	**15,538**	**19,847**
3	Number of category 1 sources tracked in Canada	**1,638**	**3,224**	**2,410**
4	Number of category 2 sources tracked in Canada	**3,920**	**9,523**	**12,881**
5	Number of category 3 sources recorded in the registry	**995**	**1,186**	**2,137**
6	Number of category 4 sources recorded in the registry	**500**	**1,312**	**1,273**
7	Number of category 5 sources recorded in the registry	**97**	**293**	**1,146**

Table 1, Item 1*: This number represents all transactions for the NSSR and SSTS systems, including new sources added by manufacturers, as well as imports and exports.*

Table 2: Sealed Source Tracking System Statistics

	SSTS Statistics	As of Dec 31, 2006	As of Dec 31, 2007	As of Dec. 31, 2008
8	Number of NSSR transactions	**30,167**	**39,645**	**40,711**
9	Number of SSTS transfers	**3,921**	**6,044**	**5,784**
10	Number of SSTS Web transactions	**368**	**873**	**3,187**
11	Number of sources that were imported into Canada	**3,846**	**5,093**	**5,763**
12	Number of sources that were exported from Canada	**6,945**	**10,476**	**11,127**

Table 2, Item 1: This number represents all transactions for the NSSR and SSTS systems, including new sources added by manufacturers, as well as imports and exports.
Table 2, Item 2: This number represents the number of sources transferred within Canada, between licensees and licensed locations.
Table 2, Item 3: This number represents the number of source transfers within Canada, as conducted by licensees using the online Web tool. The difference between lines 2 and 3 represents the number of transactions conducted by phone, fax, mail and e-mail.

Chart #2: Number of sources, by category:

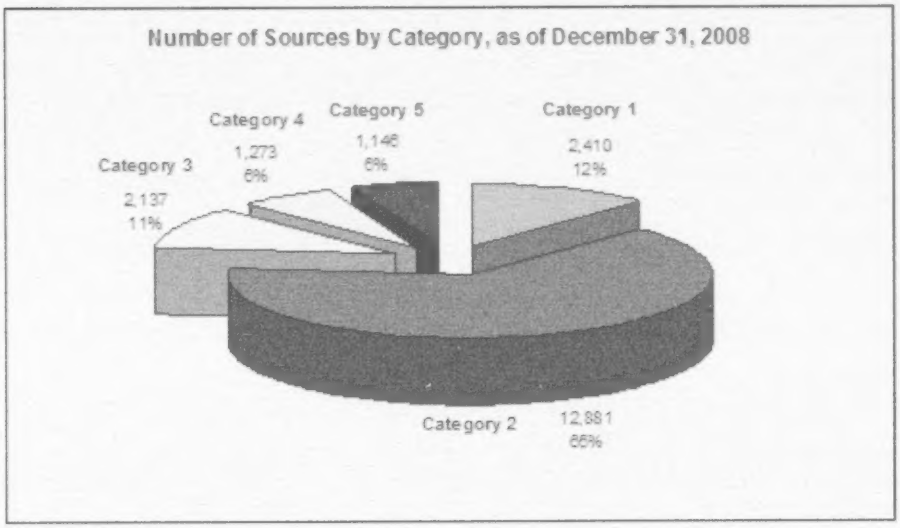
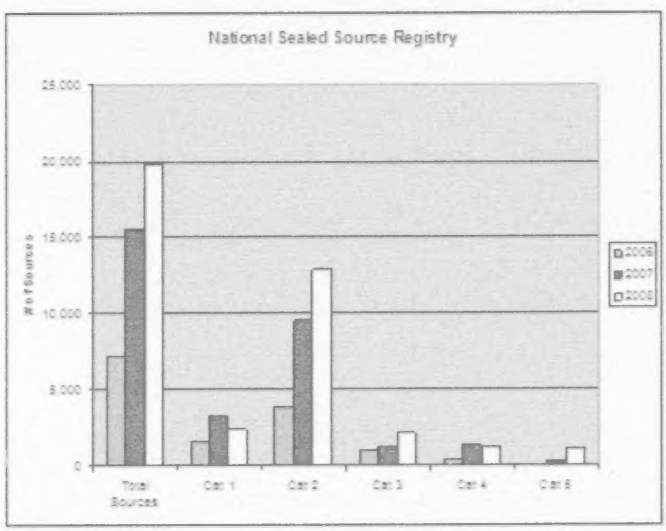


Chart #3: Number of sources by category, per year:



Phase II of the NSSR/SSTS program will add into the registry the sources from the current CNSC licensing operations database and from the licensees' reported annual inventories for category 3, 4 and 5 sources. This is expected to be completed by the end of 2009.

7. Conclusion

The tracking system contains information on the movement and location of high-risk radioactive sources in Canada, from their manufacture to their final disposition. The CNSC is the first nuclear regulator among the G8 countries to implement Web-based NSSR and SSTS systems. This

enhancement in CNSC regulatory oversight demonstrates the CNSC's tight regulatory control over high-risk radioactive sources.

The CNSC is working to enhance the existing system with an upgrade to the SSTS Web pages, by populating the NSSR with additional information on category 3, 4 and 5 sealed sources, and by further developing and implementing performance verification processes. Statistics show a 2.7% increase in the number of radioactive sealed source transactions from 2007, which indicates an ongoing improvement in the NSSR and SSTS systems' effectiveness and efficiency. This number is expected to increase in 2009, when more sources in categories 3, 4 and 5 will be included in the registry.

Appendix 1

Categorization of sources

Radioactive sealed sources are used throughout the world in medicine, industry, agriculture, research and education, and vary widely in radiological risk. In 2005, the IAEA[2] published a risk based ranking of radioactive sources and practices, divided into five categories. The category assigned to each practice or radioactive nuclear substance (contained in the sealed source) takes into account factors such as:

1. Radiological risk associated with the source;
2. The nature of the work (or application for which the source is used);
3. The mobility of the source, experience from reported accidents;
4. Typical versus unique activities within an application.

These factors were used to assign sources and practices into five categories. If not managed safely and securely, category 1 sources are considered to pose the greatest risk to human health, while category 5 sources pose the lowest risk.

Category 1 sources are classified as "personally extremely dangerous".

Category 1 (very high-risk)
This radioactive material, if not safely managed or securely protected, would be likely to cause permanent injury (in some cases, fatal) to a person handling or coming in contact with the material for a period of a few minutes. Exposure would be fatal if a person were close to it in an unshielded manner for a few minutes to an hour. Category 1 sources are associated with licensed activities to which the CNSC Class II Nuclear Facilities and Prescribed Equipment Regulations apply.

Examples of a Category 1 source usage:

- Self Shielded Irradiators: Gamma sources are used in these irradiators for experimental purposes, or as a means of sterilization. Gamma irradiation kills bacteria, by breaking down bacterial DNA and inhibiting cell division. Blood products, for example, are sterilized in self shielded irradiators.

Image #1: Cobalt-60 Gammacell.

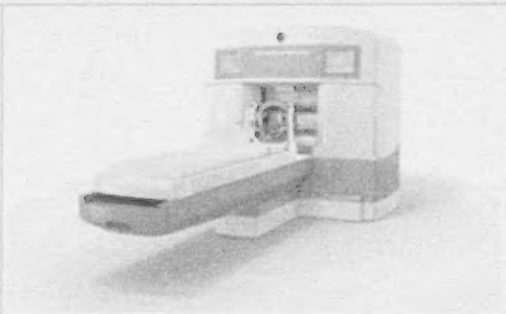


Image #2: Elekta Gamma Knife Image

#3: Gamma Knife in use

Gamma Knife Radiosurgery: An advanced form of surgery, performed with highly focused beams of radiation. As many as 201 radioactive sealed sources create intersecting beams of gamma radiation, which deliver a concentrated dose of radiation to a precise area of the brain. These radiation beams form the "knife".

- Radioactive Source Teletherapy: External beam radiotherapy, otherwise known as "teletherapy", is the most frequently used form of radiotherapy. Radiotherapy is the medical use of radiation (produced by a radioactive sealed source mounted inside the machine) as part of cancer treatment or to control malignant cells.

Image #4: Co-60 Teletherapy

Category 2 sources are classified as "personally very dangerous".

Category 2 (High-risk)
This radioactive material, if not safely managed or securely protected, could cause permanent injury to a person either handling it, or coming in contact with it for a short period of time (minutes to hours) — or may be fatal if close to it in an unshielded manner for a few days. Category 2 sources are associated with licensed activities to which the CNSC Nuclear Substances and Radiation Devices Regulations mostly apply.

Example of a Category 2 source usage:

- Industrial radiography is a non-destructive testing (NDT) application, using gamma radiation from a highly radioactive source, along with photographic film, for the detection of internal physical imperfections (such as voids, cracks, flaws, segregations, pores and inclusions) in pressure vessels, pipelines, ships and reactor components. Radiography

produces images on photographic film (similar to X-ray images), which show varying densities according to the amount of radiation absorbed in the material.

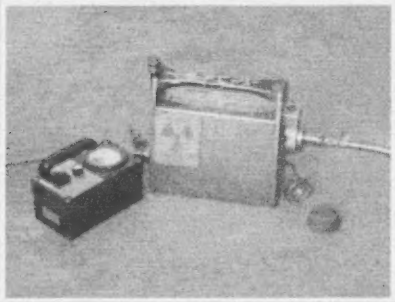


Image #5: Industrial radiography "camera" which contains the radioactive sealed source

Image #6: NDT pipeline inspection, using industrial radiography equipment

Category 3 sources are classified as "personally dangerous".

Category 3 (Moderate-Risk)

This radioactive material, if not safely managed or securely protected, could cause permanent injury to a person either handling it, or otherwise coming in contact with it for some hours. It could possibly — although unlikely — be fatal to be close to this amount of unshielded radioactive material for a period of days to weeks. Category 3 sources are associated with licensed activities to which the CNSC Nuclear Substances and Radiation Devices Regulations apply.

Examples of a Category 3 source usage:

- Industrial gauges: These gauges are usually installed in fixed positions, for measuring and process control purposes. These include density gauges, level gauges, belt mass meters, and thickness gauges. The radioactive sealed source is mounted inside the gauge and projects a radiation beam through the material, which is picked up by a detector to provide a measurement.

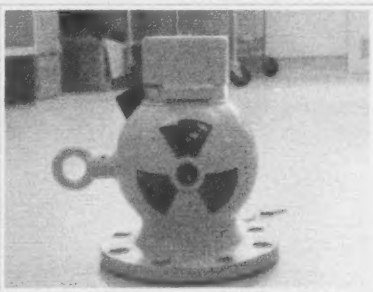


Image #7: Industrial fixed gauge

- Brachytherapy delivers a concentrated dose of radiation to cancerous tissue from within. High dose rate (HDR) brachytherapy is the placement of a small, highly radioactive sealed source, directly into cancerous tissues, for a short period of time. The procedure is sometimes guided by ultrasound or 3D computerized mapping techniques.

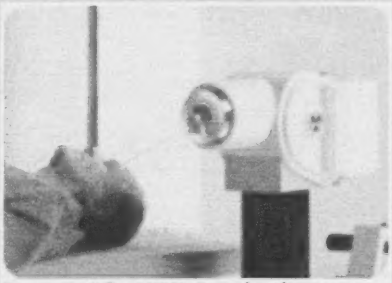


Image #8: HDR Brachytherapy

Category 4 sources are classified as "unlikely to be dangerous".

Category 4 (Low-risk)
It is very unlikely that anyone would be permanently injured by this radioactive material. However, if this unshielded radioactive material is not safely managed or securely protected, it could — although it is unlikely — temporarily injure someone either handling it, coming in contact with it, or being close to it for a period of several weeks. Category 4 sources are associated with licensed activities to which the CNSC *Nuclear Substances and Radiation Devices Regulations* apply.

Example of Category 4 source usage:

- Low dose rate industrial gauges, such as moisture and density gauges, are used to measure the density of asphalt, soil, aggregate or concrete, as well as the moisture content of soil or aggregate.

Image #9: Portable gauge

Image #10: Portable gauge in use

Category 5 sources are classified as "not dangerous".

Category 5 (Very Low-risk)
No one could be permanently injured by this amount of radioactive material. Category 5 sources are associated with licensed activities to which the CNSC *Nuclear Substances and Radiation Devices Regulations* mostly apply.

Examples of a Category 5 source usage:

- Electron capture detector Ni-63 sources are used in gas chromatography instruments. They detect minute amounts of chemical compounds, such as halogenated organic chemicals in environmental samples. Pesticide levels in foodstuffs, for example, are measured with these detectors.

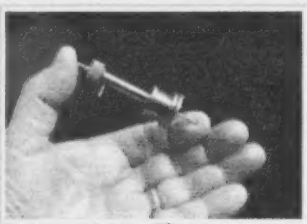


Image #11: Electron Capture Detector

- Low dose rate (LDR) brachytherapy involves exposure to small radioactive sealed sources for hours to days. Ocular melanoma is one example of a tumor that can be treated with LDR brachytherapy. In another example, radioactive seeds of iodine-125 are surgically implanted to treat prostate cancer.

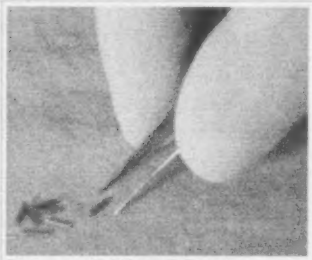


Image #12: LDR Brachytherapy

1. *"Categorization of radioactive sources", IAEA TECDOC-1344, 2003* [Return]

2. This number represents all transactions for the NSSR and SSTS systems, including new sources added by manufacturers, as well as imports and exports. [Return]